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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/530,553 | 08/04/2005 | Jean-Jacques Diaz | REGIM 3.3-052 | 7629 |

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LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

| EXAMINER | |
|---|---|
| HURT, SHARON L | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1648 | |

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| 09/21/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/530,553 | DIAZ ET AL. | |
| | Examiner | Art Unit | |
| | Sharon Hurt | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☐ Claim(s) *14-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *Nov. 03, 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of the Claims*

Claims 14-38 are pending and under examination. Claims 1-13 have been cancelled.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claim 14-38 are rejected under 35 U.S.C. 112, first paragraph**, as failing to comply with the **enablement requirement**. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states: "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring ingenuity beyond that to be expected of one of ordinary skill in the art (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150

(CCPA 1977)). The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those In the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The instant disclosure fails to meet the enablement requirement for the following reasons:

*The nature of the invention:* The claimed invention is drawn to a pharmaceutical composition comprising an inhibitor of S-adenosyl methionine decarboxylase and another agent efficient against a herpes simplex infection. The claimed invention is also drawn to preventing or treating a herpes simplex virus infection, comprising administering a medicament.

*The state of the prior art:* The art teaches that the inhibitors of S-adenosyl-methionine decarboxylase do not affect the replication of herpes simplex virus type 1 or herpes simplex virus type 2 as evidenced by Tyms et al. (Biochemical and Biophysical Research Communications, Jan. 1979, Vol. 86, No. 2, pages 312-318). The art teaches SAM486A is a polyamine inhibitor and a SAMDC inhibitor as described by Paridaens et al. (British Journal of Cancer, 2000, Vol. 83, No. 5. pages 594-601) (Abstract). The art also teaches that polyamines are essential for virus production and HSV DNA synthesis as described by Wallace et al. (FEBS Letters, April 1981, Vol. 126, No. 2, pages 157-160) (Abstract). The art further teaches that combination therapy with acyclovir and another agent is more effective against HSV and also effective in treating acyclovir-resistant HSV as described by Duan et al. (Antimicrobial Agents and Chemotherapy,

July 1998, Vol. 42, No. 7, pages 1629-1635) (Abstract). However, it does not teach that SAMDC inhibitors are effective in preventing or treating a HSV infection.

The claim contains the term "**preventing**". The office interprets these terms as denoting absolute prevention of infection of even a single cell by a virus and absolute elimination of infection of any cell by a virus. The art teaches that while there are antiviral agents which can reduce the incidence of or ameliorate the symptoms of viral infection, there are no treatment methods which can completely prevent viral infection in all cells in every subject and no antiviral agents which can completely eliminate infection in every cell of every subject.

*The amount of direction or guidance present and the presence or absence of working examples*: Given the teachings of unpredictability in the art regarding the structural and functional differences in the antiviral compounds, detailed teachings are required in the disclosure to enable the full scope of the claims. Applicant's disclosure is limited to *in vitro* data in cell culture with a SAMDC agent. The specification has an example of inhibition of HSV by only 20% to 27%. The only working examples are for SAMDC inhibitors: MGBG and Compounds I, II and III although, it is not clear of the components of Compounds I, II and III. Examples are provided for the generic MGBG; however, no examples are provided for SAM486A. The results of the Table in Example 9, representing inhibition of HSV *in cellulo* are not impressive. A working example of inhibition of HSV replication with SAM486A and acyclovir is not evident.

There are no working examples drawn to absolute prevention of viral infection *in vivo* by employing the claimed method and no working examples showing absolute prevention of

infection with viruses *in vivo*. Therefore, there is insufficient evidence to ascertain that the claimed compositions actually completely prevent or totally eliminate viral infection in humans.

*The breadth of the claims and the quantity of experimentation needed:* The claimed invention is drawn to a composition comprising a SAMDC inhibitor and another agent efficient against herpes simplex virus infection. The specification is not enabled for any agent, which may inhibit herpes simplex virus. The breadth of the claims encompasses any viral inhibitor or antiviral agent. Because the invention encompasses antiviral compounds and because the specification fails to provide guidance as to how to use the claimed method for an SAMDC inhibitor and another agent, it would require undue experimentation by one of skill in the art to be able to practice the claimed invention commensurate in scope with the claims.

Because the art teaches a high degree of unpredictability in the ability of antivirals to completely prevent or eliminate viral infection, because the claims encompass absolute prevention and elimination of all virus infections, and because the specification fails to provide an enabling disclosure for absolute prevention or complete elimination, it would require undue experimentation by one of skill in the art to be able to practice the claimed invention commensurate in scope with the claims.

## ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

September 10, 2007

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600